Group V: Claims 13-18 and 21-23 as drawn to methods of pre-screening NELL-1 modulators by measuring specific binding of said modulator to the NELL1 nucleic acid;

Group VI: Claims 25-27 and 31, drawn to methods of increasing bone mineralization by increasing endogenous NELL-1 levels by treatment with a protein;

Group VII: Claims 33-36, as drawn to methods of facilitating the repair of bone fractures by increasing the NELL-1 gene product concentration via the introduction of NELL-1 producing cells to the fracture site;

Group VIII: Claims 33-34, 37, 38, 42 and 43, as drawn to methods of facilitating the repair of bone fractures by increasing the expression of endogenous NELL-1 gene product;

Group IX: Claims 28-30, 32-34, 37, 39-43, as drawn to methods of facilitating bone remineralization and the repair of bone fractures by increasing the expression of NELL-1 through the introduction of an exogenous gene;

Group X: Claims 44 and 45, as drawn to methods of facilitating the repair of bone fracture by contacting bone fracture site with NELL-1 protein; and

Group XI: Claims 46-49, drawn to bone graft materials.

In response to this restriction requirement, Applicants provisionally elect Group I, claims 1, 2, and 8-12, with traverse.

Applicants note, however that **the restriction between Groups I and II, between Groups III, IV, and V, between Groups VI and IX, and between Groups VII and VIII is legally improper.** In making such a restriction, the Examiner effectively requires that a single claim (*e.g.*, claim 1) be divided up and presented in several applications. This flatly contravenes accepted law. As stated by the CCPA:

> As a general proposition, an applicant has a right to have ***each claim*** examined on the merits.
>
> * * *
>
> If, however, a single claim is required to be divided up and presented in several applications, that claim would never be considered on the merits. The totality of the resulting fragmentary claims would not necessarily be the equivalent of the original claim. Further, since the

> subgenera would be defined by the examiner, rather than by the applicant, it is not inconceivable that a number of the fragments would not be described in the specification.
>
> * * *
>
> §121 provides the Commissioner with the authority to promulgate rules designed to *restrict* an *application* to one of several claimed inventions, ... It does not provide a basis under the authority of the Commissioner to *reject* a particular *claim* on that same basis.
>
> * * *
>
> We hold that a rejection under §121 violates the basic right of the applicant to claim his invention as he chooses. *In Re Weber, Soder and Boksay* 198 USPQ 328, 331-332 (CCPA 1978)

See also, In Re Haas 179 USPQ 623, 624, 625 (*In Re Haas I*) and *In Re Haas* 198 USPQ 334-337 (*In Re Haas II*).

The CCPA thus recognized that an Examiner **may not** reject a particular claim on the basis that it represents "independent and distinct" inventions. *See, In re Weber Soder and Boksay, supra.* Moreover, **the CCPA recognized that imposition of a restriction requirement on a single claim is just such an improper rejection.**

In particular, the courts have definitively ruled that the statute authorizing restriction practice, *i.e.*, 35 U.S.C. §121, provides no legal authority to impose a restriction requirement on a single claim, even if the claim presents multiple independently patentable inventions. *See, In Re Weber, Soder and Boksay, In Re Haas I, and In Re Haas II.* More specifically, the CCPA expressly ruled that there is no statutory basis for rejecting a claim for misjoinder, despite previous attempts by the Patent Office to fashion such a rejection. As noted in *Weber*:

> The discretionary power to limit one applicant to one invention is no excuse at all for refusing to examine a broad generic claim-- **no matter how broad, which means no matter how many independently patentable inventions may fall within it**. [emphasis added] *In Re Weber* at 334.

Applicants recognize that instead of improperly imposing a restriction requirement on a single claim, the Office may limit initial examination to a "reasonable number" of species encompassed by the claim. *See*, 37 C.F.R. §1.146. This practice strikes an appropriate balance between the concerns of the patent office regarding administrative

concerns and unduly burdensome examination, and the clear constitutional and statutory rights of an inventor to claim an invention as it is contemplated, provided the dictates of 35 U.S.C. §112 are complied with. *See, e.g.*, the MPEP at 803.02, *In Re Wolfrum* 179 USPQ 620 (CCPA, 1973) and *In re Kuehl* 177 USPQ 250 (CCPA, 1973). Unlike a restriction requirement, a species election does not preclude an applicant from pursuing the original form of a claim in subsequent prosecution, nor does it force an applicant to file multiple divisional applications that are incapable of capturing the intended scope of the application. It should be clear that the added cost of filing and prosecuting eleven divisional patent applications in the present case does not strike an appropriate balance between the administrative concerns of the office and Applicants statutory rights as an inventor.

Finally, Applicants note that the CCPA has explicitly held that improper restriction of a single claim is a decision under the jurisdiction of the Board of Appeals, and the Federal Courts. This is in contrast to simple administrative decisions regarding ordinary restriction requirements, which are not generally subject to Appellate review. *See, In Re Haas I, supra.* Because restriction of a single claim into multiple groups is tantamount to a rejection and a refusal to examine the claim as drafted, as articulated in *Haas I*, the Board of Appeals and the courts have jurisdiction over the decision. Accordingly, **Applicants expressly reserve the right to appeal any decision that may be made regarding the present petition to the Patent Office Board of Appeals and to the Federal Circuit**.

In view of the foregoing, Applicants have established that the restriction between Groups I and II, between Groups III, IV, and V, between Groups VI and IX, and between Groups VII and VIII is legally improper and respectfully request that the restriction between these groups be withdrawn.

Applicants submit that restriction between Group I/II, Groups III/IV/V, Groups VI/IX, Groups VII/VIII, Group X, and Group XI is unnecessary. According to MPEP §803, the Examiner should examine all claims in an application, **even though they are directed to distinct inventions**, unless to do so would create a **serious burden**. In the instant case, the claims of Group I/I are drawn to methods of screening for an agent that alters NELL-1 expression, the claims of Groups III/IV/V are drawn to methods of pre-screening NELL-1 modulators, the claims of Group VI/IX are drawn to methods of increasing bone mineralization by increasing NELL-1, the claims of Group VII/VIII are drawn to methods of facilitating the repair of bone fractures by increasing NELL-1 gene product concentration, the claims of Group X are dawn to methods of facilitating the repair of bone fractures by

contacting the fracture site with NELL-1 protein and the claims of Group X are drawn to bone graft materials comprising NELL-1. All of the Groups thus recite a NELL-1 nucleic acid or protein. A search for prior art relevant to NELL-1 is therefore expected to identify any prior art, if such exists, relevant to all of the above-identified Groups. A search for prior art relevant to all of the Groups thus entails no greater effort than a search for prior art relevant to a single Group. Thus, examination of Groups I through XI. Accordingly, there is no "serious burden, and the restriction between Groups I through XI should be withdrawn.

In conclusion, **the restriction between Groups I and II, between Groups III, IV, and V, between Groups VI and IX, and between Groups VII and VIII is legally improper.** In addition, the restriction between Groups I through XI is unnecessary because examination of all of these groups together does not create a "serious burden." Thus, Applicants respectfully request that the restriction requirement be withdrawn.

If a telephone conference would expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (415) 217-6021.

Respectfully submitted,

Tom Hunter
Attorney for Applicant(s)
Reg. No. 38,498

Encl: 1) Change of correspondence address.
2) Petition for 1 month extension of time.